DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0385]

Guidance on the Petition Process to Request Approval of Labeling for Foods That Have Been Treated By Irradiation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Guidance; Implementation of Section 10809 of the Farm Security and Rural Investment Act of 2002, Pub. L. No. 107–171, § 10809 (2002) Regarding the Petition Process to Request Approval of Labeling for Foods That Have Been Treated By Irradiation," which explains the recommended process for petitioning the agency for approval of labeling, which is not false or misleading in any material respect, of a food that has been treated by irradiation.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–822), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document implementing the part of section 10809 of the Farm Security and Rural Investment Act of 2002 (Public Law 107–171, § 10809 (2002)), that states that "[p]ending promulgation of the final rule * * *, any person may petition the Secretary [FDA] for approval of labeling, which is not false or misleading in any material respect, of a food which has been treated by irradiation using radioactive isotope, electronic beam, or x-ray." Section 10809 of the Farm Security and Rural Investment Act of 2002 also requires that, pending promulgation of the final rule, "[t]he Secretary [FDA] shall approve or deny such a petition within 180 days of receipt of the petition, or the petition shall be deemed denied, except to the extent additional agency review is mutually agreed upon by the Secretary [FDA] and the petitioner."

FDA is issuing this guidance to interested parties who wish to petition the agency for approval of the labeling of a food treated by irradiation. As explained in the guidance, FDA recommends that interested parties who wish to petition the agency use the procedures set forth in § 10.30 (21 CFR 10.30), except that § 10.30(e)(2)(iii), regarding 180-day tentative responses, does not apply, because section 10809 of the Farm Security and Rural Investment Act of 2002 provides that the petition is deemed denied if the Secretary (FDA) fails to act on the petition within 180 days of its receipt, unless the parties mutually agree upon an extension.

This guidance is a level 1 guidance issued consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)). The agency is soliciting public comment, but is implementing this guidance document immediately in accordance with § 10.115(g)(2) because the agency has determined that prior public participation is not feasible or appropriate. The Farm Security and Rural Investment Act of 2002 (Public Law 107–171) was enacted on May 13, 2002, and section 10809 is now in effect and must be implemented immediately. Thus, there is a pressing need for guidance to help effect such implementation. Accordingly, FDA is making this guidance effective immediately. This guidance represents the agency's current thinking on this subject. It

does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in citizen petitions under § 10.30 is approved under OMB control number 0910–0183.

III. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on this guidance at any time. Groups or organizations must submit two copies of any written comments. Individuals may submit one copy of their comments. Identify your written comments by placing the docket number at the top of your comment(s). If you base your comments on scientific evidence or data, please submit copies of the specific information along with your comments. Any comments submitted will be filed under the docket number identified in brackets in the heading of this document. The guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http:/www.cfsan.fda.gov/~dms/guidance.html.

Dated: September 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

BILLING CODE 4160–01–S